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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional): 22727/04125

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on July 27, 2009

Signature /milan jovanovic/

Typed or printed name Milan Jovanovic

Application Number	Filed
10/617,078	July 10, 2003

First Named Inventor: Steven P. Schwendeman

Art Unit	Examiner
1617	Betton, Timothy E.

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- ☐ attorney or agent of record. Registration number _____.
- ☑ attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 60,798

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614-621-7768
Telephone number

July 27, 2009
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☑ *Total of 1 forms are submitted.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	
Schwendeman *et al.*	Group Art Unit: 1617
Application No.: 10/617,078	Confirmation No.: 3384
Filed: July 10, 2003	Examiner: Betton, Timothy E.
For: **ANTIGEN-POLYMER COMPOSITIONS**	Attorney Docket No.: 22727/04125

PRE-APPEAL BRIEF REQUEST FOR REVIEW

This paper is filed together with a Notice of Appeal and Pre-Appeal Brief Request for Review. The review is requested for the reasons stated below.

Claims 1-6 and 27-62 are pending in the instant application and claims 27-29 stand as withdrawn from consideration. The Office rejected claims 1-6 and 30-62.

Rejections – 35 U.S.C. § 103(a)

The Office has rejected claims 1-3, 5, and 6 under 35 U.S.C. § 103(a) as being unpatentable over Andrianov *et al.* (USPN 5,529,777) in view of Sokoll *et al.* (USPN 6,228,423 B1). The Office has asserted that Andrianov teaches a method of eliciting an immune response as in claim 1 of the instant application, wherein: PLGA is the biodegradable polymer microparticle of claim 1; a peptide, among other disclosed antigens, is the one or more antigens also of claim 1; and, magnesium incorporated with a polyelectrolyte preparation is the encapsulated one or more basic additives also of claim 1. The Office stipulates that Andrianov does not teach the basic additive of magnesium carbonate. However, the Office refers to Sokoll, which it asserts teaches magnesium carbonate as a normally employed excipient for oral formulations. In conclusion, the Office states that:

> "it would have been prima facie obvious to one of ordinary skill in the art to modify the invention of Andrianov et al. to accommodate the disclosure of magnesium carbonate in the formulation as in Sokoll et al. Both referenced. [*sic*] patents teach a PLGA directed to delivery of an antigen to a specific region in a mammal. Therefore, it would at once have been obvious to combine both references due to their relative similarity in scope of invention, i.e., delivery of antigen by a polymeric delivery system."

Office Action mailed September 30, 2008, page 6, and Office Action mailed March 26, 2009, page 5.

Applicant respectfully traverses the rejection. There are only 2 references to magnesium in Andrianov, in the first full paragraph of column 7 and the fourth full paragraph of column 11. Both references to magnesium in Andrianov relate to the use of divalent and trivalent metal ions to crosslink the polymers used to make microspheres, i.e., magnesium is used as a crosslinking agent. There is no reference in Andrianov that addition of magnesium in any way influences immune response. In fact, Andrianov discloses that an effect of the crosslinking agents is to regulate the release of antigen from the microspheres. *See* Andrianov, Column 18, first and second full paragraphs. Furthermore, Andrianov discloses various adjuvants for enhanced immunogenicity and does not include magnesium or any other basic additive as an adjuvant. *See* Andrianov, Column 13, first 4 full paragraphs. It is clear that Andrianov contemplates the use of magnesium as a crosslinking agent to control the release of an antigen from a microsphere, NOT as an adjuvant for increasing immunogenicity of the antigen as in the claimed invention.

Furthermore, the reference to Sokoll must be analyzed in its entirety. The reference to magnesium carbonate in Sokoll refers to use of magnesium carbonate as an excipient for oral formulations. Sokoll, Column 11, fourth full paragraph. Sokoll further discloses that protection from an acidic environment is obtained via administration of an acid neutralizing preparation before, concomitant with, or directly after oral administration of the microparticles. Sokoll, Column 11, fifth full paragraph. It is clear that Sokoll does not disclose the use of magnesium carbonate to enhance immunogenicity, but rather as an excipient. *Taber's Cyclopedic Medical Dictionary* defines "excipient" as any substance added to a medicine to permit it to be formed into the proper shape and consistency; the vehicle for the drug. Clearly, Sokoll does not disclose

magnesium carbonate for a method to enhance an immunogenic response as in the claimed invention.

These distinctions are vital to a proper obviousness analysis under *Graham*, as factor 1 is determining the scope and content of the prior art, and factor 2 is ascertaining the differences between the prior art and the claims in issue. *Graham v. John Deere Co.*, 148 USPQ 459 (1966). Applicant respectfully asserts that the Office has not properly determined the scope and content of Andrianov and Sokoll, nor has the Office properly ascertained the differences between the prior art and the claims at issue. Therefore, the Office has not established a prima facie case of obviousness.

Furthermore, Applicant again respectfully submits that one of ordinary skill in the art would have no reason whatsoever to combine the teachings of Andrianov and Sokoll in the absence of the instant claims. Neither Andrianov or Sokoll identify a problem that would cause one of ordinary skill to look to another reference to solve. Also, one of ordinary skill in art would not look to Sokoll's use of magnesium carbonate as an excipient as a replacement for Andrianov's use of magnesium as a crosslinking agent to form a microsphere. The disclosed uses of magnesium in Andrianov and Sokoll are not analogous in any way, nor would they render obvious the claimed invention. Applicants respectfully request withdrawal of the rejection.

The Office has rejected claim 4 under 35 U.S.C. § 103(a) as being unpatentable over Schoch, E.P. (Industrial and Engineering Chemistry; Direct Titrometric Methods for Magnesium, Calcium, and Sulfate Ions and Their Application in Water Analysis; 1926, Vol. 19, No. 1, page 112) and CHEMTUTOR, LLC Acids and Bases; The 5% Rule, Copyright 1997, page 17, in view of Lenntech (Magnesium and water, Chemical Properties, Health and Environmental Effects; Copyright 1998, page 1). The Office has asserted that Schoch teaches pH value ranges for magnesium and magnesium ion as encompassed in claim 4 of the instant application, CHEMTUTOR teaches the measurement of pH in medicine, which is disclosed at 37°C, and Lenntech teaches water solubility of magnesium carbonate. In conclusion, the Office states it would have been prima facie obvious for one of ordinary skill in the art to combine the art disclosed in Schoch with that of CHEMTUTOR and Lenntech.

Applicant respectfully traverses the rejection. The Office is reminded that a dependent claim necessarily imports all of the limitations of the claim from which it depends. In the instant case, claim 4 depends from claim 2, which depends from claim 30, which depends from claim 1. Therefore, all the limitations of claims 1, 30, and 2 are necessarily present in claim 4 as if fully re-written therein. It is this combination that must be compared to the prior art, exactly as if it were presented as one independent claim. M.P.E.P. § 608.01(n) III, fourth full paragraph. There is nothing in Schoch, CHEMTUTOR, and Lenntech that discloses methods of enhancing an immunogenic response in a mammalian subject, or administering microparticles of a biodegradable polymer, or that the microparticles comprise a biologically effective amount of one or more antigens, or that the microparticles also encapsulate one or more basic additives as disclosed in claim 1, and which are imported into dependent claim 4 along with the limitations of claims 30 and 2. Applicant respectfully asserts that claim 4 is not prima facie obvious in light of the teachings of Schoch, CHEMTUTOR, and Lenntech, as the Office has not shown that the cited references teach each and every element and limitation of claim 4, and requests withdrawal of the rejection.

The Office has rejected claims 30-62 under 35 U.S.C. § 103(a) as being unpatentable over Elahi *et al.* (USPN 4,280,816), Wright *et al.* (USPN 6,379,704 B2), and Thanavala *et al.* (Affinity, Cross-Reactivity, and Biological Effectiveness of Rabbit Monoclonal Antibodies Against a Synthetic 37 Amino Acid C-Terminal Peptide of Human Chorionic Gonadotropin, Clin. Exp. Immunol. (1980) 39, 112-118), in view of Setterstrom *et al.* (USPN 6,309,669 B1).

Applicant respectfully traverses the rejection. The Office is again reminded that a dependent claim necessarily imports all of the limitations of the claim from which it depends. In the instant case claim 30 depends from claim 1. Therefore, dependent claim 30, as well as all claims the depend from claim 30, necessarily import all of the limitations of claim 1. It is this combination that must be compared to the prior art, exactly as if it were presented as one independent claim. M.P.E.P. § 608.01(n) III, fourth full paragraph. The Office does not make one single mention in its analysis of Elahi, Wright, Thanavala, and Setterstrom as applied to claims 30-62 of the requirement of a basic additive as disclosed in instant claim 1 and therefore imported into claim 30 and all other dependent claims. Applicant respectfully asserts that claims

30-62 are not prima facie obvious in light of the teachings of Elahi, Wright, Thanavala, and Setterstrom, as the Office has not shown that the cited references teach each and every element and limitation of claims 30-62, and requests withdrawal of the rejection.

It is believed that there is no fee or no additional fee associated with the filing and consideration of this document; however, should the Commissioner decide that any fee or fee deficiency is due, the Commissioner is hereby authorized to charge any and all fees incurred as a result of entering or considering this document to deposit account number 03-0172.

Respectfully submitted,

Calfee, Halter & Griswold LLP

Date: July 27, 2009

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